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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/358,788  | 07/22/1999  | MICHAEL J. HELLER    | 0031/81494/JPW/GC   | 1976             |
| 23432 7590 05/27/2011<br>COOPER & DUNHAM, LLP<br>30 Rockefeller Plaza<br>20th Floor<br>NEW YORK, NY 10112 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| FORMAN, BETTY J   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1634  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 05/27/2011  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

09/358,788

**Applicant(s)**

HELLER ET AL.

**Examiner**

Betty Forman

**Art Unit**

1634

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49.57.58 and 79-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49.57.58 and 79-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 May 2011 has been entered.

### ***Status of the Claims***

2. This action is in response to papers filed 6 May 2011 in which claim 49 was amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 6 January 2011 are withdrawn in view of the amendments.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 49, 57-58 and 79-81 are under prosecution.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 49, 57-58 and 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,017,696 in view of Cozzette (U.S. Patent No. 5,063,081).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets. The claim sets merely differ in the arrangement of limitations within the claim sets. For example, independent Claim 49 of the instant claim set defines electronic stringency control while dependent Claims 7, 15 and 45 of the '696 claim set provides this limitation. The claim sets further differ in that the instant claims further define the microlocations as comprising permeation and attachment layers.

Cozzette teaches a method similar to the patent comprising immobilizing a binding partner (e.g. DNA) onto one of a plurality of electrodes, contacting with the complementary binding partner and detecting the interaction (Column 52, lines 4-20). Cozzette further teaches the method includes adding a probe complementary to a portion of the target that is not hybridized to the immobilized probe in a sandwich format and detecting formation of the sandwich (Column 52, lines 11-15). Cozzette also teaches that the permselective layer also acts as an adhesion promoter for the attachment layer thereby facilitating biomolecule immobilization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the permselective and attachment layers of Cozzette to the patent electrodes. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of

Cozzette. The artisan would have been further motivated to do so for the expected benefits of providing a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest and facilitating biomolecule immobilization as desired in the art (Cozzette, paragraph spanning columns 13-14).

5. Claims 49, 57-58 and 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,048,690 in view of Cozzette (U.S. Patent No. 5,063,081).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets. The claim sets merely differ in that the instant claims define the structure of the electronic stringency control device e.g. microlocations comprising permeation and attachment layers while the patent is silent reading the structure.

However, Cozzette teaches the structure of the electronic device including a permselective layer also acts as an adhesion promoter for the attachment layer thereby facilitating biomolecule immobilization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the permselective and attachment layers of Cozzette to the patent electrodes. One of ordinary skill in the art would have been

motivated to do so with a reasonable expectation of success based on the teachings of Cozzette. The artisan would have been further motivated to do so for the expected benefits of providing a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest and facilitating biomolecule immobilization as desired in the art (Cozzette, paragraph spanning columns 13-14).

6. Claims 49, 57-58 and 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 5,849,486 in view of Cozzette (U.S. Patent No. 5,063,081).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets. The claim sets merely differ in that the instant claims define the structure of the electronic stringency control device e.g. microlocations comprising permeation and attachment layers while the patent is silent reading the structure. However, Cozzette teaches the structure of the electronic device including a permselective layer also acts as an adhesion promoter for the attachment layer thereby facilitating biomolecule immobilization (paragraph spanning columns 13-14).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the permselective and attachment layers of

Cozzette to the patent electrodes. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Cozzette. The artisan would have been further motivated to do so for the expected benefits of providing a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest and facilitating biomolecule immobilization as desired in the art (Cozzette, paragraph spanning columns 13-14).

7. Claims 49, 57-58 and 79-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,582,421.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method for analyzing a nucleic acid sample by hybridization on electronically addressable microlocations comprising a permeation layer wherein hybridization stringency is electronically controlled to remove non-specifically hybridized targets.

The claim sets merely differ in the arrangement of limitations within the claim sets. For example, independent Claim 49 of the instant claim set defines electronic stringency control while dependent Claim 8 of the patent provides this limitation. The claim sets further differ in that the patent defines additional steps of fluorescent labeling and detection. However, the open claim language "comprising" of the instant claims



encompasses the additional elements of the patent claims. Therefore the instant claims are generic to the patent claims and therefore an obvious embodiment.

***Conclusion***

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Forman whose telephone number is (571)272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1634

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